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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/984,178	12/03/97	HORVITZ	H	01997198006

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EXAMINER	
WILSON,M	
ART UNIT	**PAPER NUMBER**
1633	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

*U.S. GPO: 1998 437-638/80022

2-16-99

Office Action Summary	Application No. 08/984,178	Applicant(s) Horvitz et al.
	Examiner Wilson, Michael C.	Group Art Unit 1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-68* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-68* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 8-15, 17, 18, 21, 22, 25-27, 33, 35-36 and 40, drawn to DNA, classified in class 536, subclass 23.1.

II. Claims 5, 6, 16 and 19, drawn to protein, classified in class 530, subclass 350.

III. Claims 7, 20 and 28, drawn to antibodies, classified in class 530, subclass 387.1.

IV. Claims 23-25, drawn to a method of identifying a cell death gene by hybridization, classified in class 435, subclass 6.

V. Claims 26-27, drawn to a method of identifying a cell death gene by PCR, classified in class 435, subclass 91.2.

VI. Claims 29-32, drawn to a method of identifying a cell death gene by using a transgenic nematode, classified in class 800, subclass 3.

VII. Claim 28, drawn to a method of identifying a cell death gene by using antibodies, classified in class 436, subclass 500.

VIII. Claims 34, drawn to a method of identifying a mutation in a cell death gene, classified in class 800, subclass 3.

IX. Claims 37-39, drawn to a method of identifying a gene which affects the activity of a cell death gene, classified in class 800, subclass 3.

X. Claims 41-43, drawn to a method of identifying an agent which mimics the activity of a cell death gene using a transgenic nematode, classified in class 800, subclass

XI. Claim 45-50, drawn to a method of identifying an agent which affects the activity of a cell death gene, classified in class 800, subclass 3.

XII. Claims 44, drawn to agents that mimics the activity of a cell death gene, classified in various classes and subclasses such as 514/44 and 424/130.1.

XIII. Claims 51 and 52, drawn to agents that affect the activity of a cell death gene, classified in class , subclass .

XIV. Claims 53-56, 64 and 65, drawn to a method of increasing the cell death gene activity by administration of an agent, classified in class , subclass .

XV. Claims 53-55 and 57-68, drawn to a method of decreasing the cell death gene activity by administration of an agent, classified in class , subclass .

2. The inventions are distinct, each from the other because of the following reasons:

Some inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation.

Some inventions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product

as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

The inventions of Groups I and II are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The protein can be used to isolate antibodies.

Groups I and III are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The antibody can be used to detect protein.

Groups I and IV, V, VI and VII are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein (Group I). The method of identifying a cell death gene (Groups IV, V, VI and VII) can be used to screen for cell death genes.

Groups I and VIII are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The method of identifying a mutation in a cell death gene can be used to screen nematodes with a cell death gene mutation.

Groups I and IX are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The method of identifying a gene that affects the activity of a cell death gene can be used to screen for such genes.

Groups I and X are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The method of identifying an agent that mimics the activity of a cell death gene can be used to screen for such agents.

Groups I and XI are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The method of identifying an agent that affects the activity of a cell death gene can be used to screen for such agents.

Groups I and XII are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The agents that mimic the activity of a cell death gene can be used to cause cell death.

Groups I and XIII are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The agents that affect the activity of a cell death gene can be used to prevent cell death.

Groups I and XIV are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The method of increasing the cell death gene activity can be used to cause increase cell death.

Groups I and XV are unrelated because the different inventions have different uses. In the instant case the DNA can be used to make protein. The method of decreasing the cell death gene activity can be used to cause decrease cell death.

Groups II and III are unrelated because the different inventions have different uses. In the instant case the protein can be used to study protein-ligand binding interactions. The antibody can be used to detect protein.

Groups II and IV, V, VI and VII are unrelated because the different inventions have different uses. In the instant case the protein (Group II) can be used to isolate antibodies. The method of identifying a cell death gene (Groups IV, V, VI and VII) can be used to screen for cell death genes.

Groups II and VIII are unrelated because the different inventions have different uses. In the instant case the protein can be used to isolate antibodies. The method of identifying a mutation in a cell death gene can be used to screen nematodes with a cell death gene mutation.

Groups II and IX are unrelated because the different inventions have different uses. In the instant case the protein can be used to isolate antibodies. The method of identifying a gene that affects the activity of a cell death gene can be used to screen for such genes.

Groups II and X are unrelated because the different inventions have different uses. In the instant case the protein can be used to isolate antibodies. The method of identifying an agent that mimics the activity of a cell death gene can be used to screen for such agents.

Groups II and XI are unrelated because the different inventions have different uses. In the instant case the protein can be used to isolate antibodies. The method of identifying an agent that affects the activity of a cell death gene can be used to screen for such agents.

Groups II and XII are unrelated because the different inventions have different uses. In the instant case the protein can be used to isolate antibodies. The agents that mimic the activity of a cell death gene can be used to cause cell death.

Groups II and XIII are unrelated because the different inventions have different uses. In the instant case the protein can be used to isolate antibodies. The agents that affect the activity of a cell death gene can be used to prevent cell death.

Groups II and XIV are unrelated because the different inventions have different uses. In the instant case the protein can be used to isolate antibodies. The method of increasing the cell death gene activity can be used to cause increase cell death.

Groups II and XV are unrelated because the different inventions have different uses. In the instant case the protein can be used to isolate antibodies. The method of decreasing the cell death gene activity can be used to cause decrease cell death.

Groups III and IV, V, VI and VII are unrelated because the different inventions have different uses. In the instant case the antibodies can be used to isolate protein. The method of identifying a cell death gene (Groups IV, V, VI and VII) can be used to screen for cell death genes.

Groups III and VIII are unrelated because the different inventions have different uses. In the instant case the antibodies can be used to isolate protein. The method of identifying a mutation in a cell death gene can be used to screen nematodes with a cell death gene mutation.

Groups III and IX are unrelated because the different inventions have different uses. In the instant case the antibodies can be used to isolate protein. The method of identifying a gene that affects the activity of a cell death gene can be used to screen for such genes.

Groups III and X are unrelated because the different inventions have different uses. In the instant case the antibodies can be used to isolate protein. The method of identifying an agent that mimics the activity of a cell death gene can be used to screen for such agents.

Groups III and XI are unrelated because the different inventions have different uses. In the instant case the antibodies can be used to isolate protein. The method of identifying an agent that affects the activity of a cell death gene can be used to screen for such agents.

Groups III and XII are unrelated because the different inventions have different uses. In the instant case the antibodies can be used to isolate protein. The agents that mimic the activity of a cell death gene can be used to cause cell death.

Groups III and XIII are unrelated because the different inventions have different uses. In the instant case the antibodies can be used to isolate protein. The agents that affect the activity of a cell death gene can be used to prevent cell death.

Groups III and XIV are unrelated because the different inventions have different uses. In the instant case the antibodies can be used to isolate protein. The method of increasing the cell death gene activity can be used to cause increase cell death.

Groups III and XV are unrelated because the different inventions have different uses. In the instant case the antibodies can be used to isolate protein. The method of decreasing the cell death gene activity can be used to cause decrease cell death.

Group IV and V are unrelated because the different inventions have different modes of operation. In the instant case a method of identifying a cell death gene by hybridization requires separate protocols and reagents than by PCR. Hybridization relies on the detection of a gene based on the annealing of a DNA probe, whereas PCR requires the annealing of primers and the polymerization of DNA. Hybridization is not required to perform PCR and PCR is not required to perform hybridization.

Group IV and VI are unrelated because the different inventions have different modes of operation. In the instant case a method of identifying a cell death gene by hybridization requires separate protocols and reagents than by using a transgenic nematode. Hybridization relies on the detection of a gene based on the annealing of a DNA probe, whereas a transgenic nematode requires microinjection of embryonic stem cells or zygotes. Hybridization is not required to create transgenic nematodes and transgenic nematodes are not required for hybridization.

Group IV and Group VII are unrelated because the different inventions have different modes of operation. In the instant case a method of identifying a cell death gene by hybridization requires separate protocols and reagents than by using antibodies. Hybridization relies on the detection of a gene based on the annealing of a DNA probe, whereas using antibodies to detect a

gene requires binding of an antibody to a protein. Hybridization is not required to use antibodies to detect a gene and antibodies are not required for hybridization.

Group IV-VII and Group VIII are unrelated because the different inventions have a different functions. A method of identifying a cell death gene may function to identify a persons heritage by identifying the presence or absence or a particular allele of a cell death gene. A method of identifying a mutation in the cell death gene may function to identify a disease associated with the cell death gene. A method of identifying a persons heritage is not required to identify disease and a method of identifying a disease is not required to identify a person's heritage.

Groups IV-VII and IX are unrelated because the different inventions have a different functions. A method of identifying a cell death gene may function to identify a persons heritage by identifying the presence or absence or a particular allele of a cell death gene. A gene that affects the activity of a cell death gene may have other activities unrelated to the cell death gene.

Groups IV-VII and X are unrelated because the different inventions have a different functions. A method of identifying a cell death gene may function to identify a persons heritage by identifying the presence or absence or a particular allele of a cell death gene. The method of identifying an agent that mimics the activity of a cell death gene may have various activities unrelated to the cell death gene.

Groups IV-VII and XI are unrelated because the different inventions have a different functions. A method of identifying a cell death gene may function to identify a persons heritage

by identifying the presence or absence or a particular allele of a cell death gene and does not require the method of identifying an agent which affects the activity of a cell death gene which can used to identify therapeutic compounds.

Groups IV-VII and XII are unrelated because the different inventions have a different uses. A method of identifying a cell death gene may function to identify a persons heritage by identifying the presence or absence or a particular allele of a cell death gene and does not require an agent that mimics the activity of a cell death gene which can be used to kill cells.

Groups IV-VII and XIII are unrelated because the different inventions have a different functions. A method of identifying a cell death gene may function to identify a persons heritage by identifying the presence or absence or a particular allele of a cell death gene and does not require an agent that affects the activity of a cell death gene which can be used to kill cells.

Groups IV-VII and XIV-XV are unrelated because the different inventions have a different functions. A method of identifying a cell death gene may function to identify a persons heritage by identifying the presence or absence or a particular allele of a cell death gene and does not require a method of increasing or decreasing cell death gene activity which can be used to kill cells.

Groups V and VI are unrelated because the different inventions have different modes of operation. In the instant case a method of identifying a cell death gene by PCR requires separate protocols and reagents than by using a transgenic nematode. PCR requires the annealing of primers and the polymerization of DNA while using a transgenic nematode requires microinjection

of embryonic cells. The transgenic nematode is not required to perform PCR and PCR is not required to create the transgenic nematode.

Groups V and VII are unrelated because the different inventions have different modes of operation. In the instant case a method of identifying a cell death gene by PCR requires separate protocols and reagents than by using antibodies. PCR requires the annealing of primers and the polymerization of DNA while using antibodies requires hybridomas and methods of isolating antibodies. The antibodies are not required to perform PCR and PCR is not required to use the antibodies.

Groups VI and VII are unrelated because the different methods have different modes of operation. In the instant case a method of using a transgenic nematode requires microinjection of embryonic cells while a method using antibodies requires hybridomas and antibody isolation techniques.

Groups VIII and IX-X are unrelated because the methods have different uses. A method of identifying a mutation in the cell death gene may function to identify a disease associated with the cell death gene. A gene that affects the activity of a cell death gene may have other activities unrelated to the cell death gene. The method of identify mutations does not require the method of identifying genes that affect cell death gene activity.

Groups VIII and XI are unrelated because the methods have different uses. A method of identifying a mutation in the cell death gene may function to identify a disease associated with the cell death gene. An agent that affects the activity of a cell death gene may have other uses

unrelated to the cell death gene, such as a protein used to isolate antibodies. The method of identify mutations does not require the method of identifying agents that affect cell death gene activity.

Groups VIII and XII are unrelated because the methods have different uses. A method of identifying a mutation in the cell death gene may function to identify a disease associated with the cell death gene. An agent that mimics the activity of a cell death gene may have other uses unrelated to the cell death gene, such as a protein used to isolate antibodies. The method of identify mutations does not require the method of identifying agents that mimic cell death gene activity.

Groups VIII and XIII are unrelated because the methods have different uses. A method of identifying a mutation in the cell death gene may function to identify a disease associated with the cell death gene. An agent that affects the activity of a cell death gene may have other uses unrelated to the cell death gene, such as a protein used to isolate antibodies. The method of identify mutations does not require the method of identifying agents that affect cell death gene activity.

Groups VIII and XIV-XV are unrelated because the methods have different uses. A method of identifying a mutation in the cell death gene may function to identify a disease associated with the cell death gene. A method of increasing or decreasing cell death gene activity which can be used to kill cells. A method of identifying a mutation in a gene is not required for a method of altering gene activity and vice versa.

Groups IX and X are unrelated because the methods have different modes of operation. A method of identifying a gene which affects a gene requires materially separate protocols and reagents than methods of identifying an agent which mimics the activity of a gene. The agent may be a protein, organic chemicals or metal. The method of identifying a gene is not required to identify all agents.

Groups IX and XI are unrelated because the methods have different modes of operation. A method of identifying a gene which affects a gene requires materially separate protocols and reagents than methods of identifying an agent which affects the activity of a gene. The agent may be a protein, organic chemicals or metal. The method of identifying a gene is not required to identify all agents.

Groups IX and XII are unrelated because the methods have different uses. A method of identifying a gene which affects a gene can be used to identify a disease while an agent that mimics the cell death gene can be used to treat disease. The method of identifying a gene is not required for the agent and the agent is not required for the method of identifying a gene.

Groups IX and XIII are unrelated because the methods have different uses. A method of identifying a gene which affects a gene can be used to identify a disease while an agent that affects the cell death gene can be used to treat disease. The method of identifying a gene is not required for the agent and the agent is not required for the method of identifying a gene.

Groups IX and XIV-XV are unrelated because the methods have different uses. A method of identifying a gene which affects a gene can be used to identify a disease while a method

of increasing or decreasing cell death gene activity which can be used to kill cells. A method of identifying a gene which affects a gene is not required for a method of altering gene activity and vice versa.

Groups X and XI are unrelated because the methods have different uses and different modes of operation. A method of identifying an agent whose activity is similar to a cell death gene would require material distinct reagents and protocols than a method of identifying an agent whose activity affect the cell death gene. The method of identifying an agent whose activity is similar to a cell death gene is not required for a method of identifying an agent whose activity affects the cell death gene. The method of identifying an agent whose activity affects the cell death gene is not required for a method of identifying an agent whose activity is similar to a cell death gene.

Groups X and XII are unrelated because the method and the agent have different functions. The method of identifying an agent which mimics the cell death gene functions to merely identify an agent while the agent can function in many ways including therapeutic purposes. The method and agent are not capable of use together.

Groups X and XIII are unrelated because the method and the agent have different functions. The method of identifying an agent which mimics the cell death gene functions to merely identify an agent while the agent can function in many ways including therapeutic purposes. The method and agent are not capable of use together.

Groups X and XIV-XV are unrelated because the method of identifying an agent which mimics the cell death gene and the method of increasing or decreasing the cell death gene activity by administering an agent are of different uses. The method of identifying an agent which mimics the cell death gene can be used to identify agents while a method of altering the cell death gene activity can be for therapeutic purposes. The methods of the two groups require distinctly separate reagents and protocols and are not capable of use together.

Group XI and XII are unrelated because a method of identifying an agent whose activity affects the cell death gene and an agent that mimics the activity of a cell death gene are of different uses. The method of identifying an agent whose activity affects the cell death gene is used to identify agents while the agent can be used for therapeutic purposes. The method of identifying an agent whose activity affects the cell death gene does not require an agent that mimics the cell death gene and an agent that mimics the cell death gene does not require the method of identifying an agent whose activity affects the cell death gene.

Groups XI and XIII are unrelated because a method of identifying an agent whose activity affects the cell death gene and an agent that affects the activity of a cell death gene are of different uses. The method of identifying an agent whose activity affects the cell death gene is used to identify agents while the agent can be used for therapeutic purposes. The method of identifying an agent whose activity affects the cell death gene does not require an agent that affects the activity of a cell death gene and an agent that affects the activity of a cell death gene does not require the method of identifying an agent whose activity affects the cell death gene.

Groups XI and XIV-XV are unrelated because the method of identifying an agent whose activity affects the cell death gene can be used to identify agents and the method of increasing or decreasing cell death gene activity is a method of using the agents. The method of identifying and the method of using the agents require separate and distinct protocols and reagents. The method of identifying is not required for the method of using the agents and the method of using the agents is not required for the method identifying the agents.

Groups XII and XIII are unrelated because an agent that mimics the activity of the cell death gene and an agent that affects activity of the cell death gene have a different functions and activities. The agent that mimics is not required for the agent that affects the cell death gene.

Groups XII and XIV-XV are unrelated because an agent that mimics the activity of the cell death gene and the method of increasing or decreasing cell death gene activity are of different uses. The agent can be used to isolate antibody if its a protein while the method of altering the cell death gene activity can be used as therapy. The agent is not required for the method and the method is not required for the agent.

Groups XIII and XIV-XV are unrelated because an agent that affects activity of the cell death gene and the method of increasing or decreasing cell death gene activity are of different uses. The agent can be used to isolate antibody if its a protein while the method of altering the cell death gene activity can be used as therapy. The agent is not required for the method and the method is not required for the agent.

Group XIV and XV are unrelated because the method of increasing cell death gene activity and the method of decreasing cell death gene activity have different uses. The method of increasing cell death gene activity can be used to create a model to identify drugs that effect cell death gene activity while a method of decreasing a cell death gene can be used to treat a disease in a patient. The method of increasing the cell death gene activity is not required to decrease the cell death gene activity and the method of decreasing the cell death gene activity is not required to increase the cell death gene activity.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group is not required for Group , restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. The inventions of Group XIV contains claims directed to the following patentably distinct species of the claimed invention:

1) treatment with an agent that is a) DNA, b) RNA or c) protein.

Should applicants elect Group XIV, applicants should elect a, b or c.

The inventions of Group XV contains claims directed to the following patentably distinct species of the claimed invention:

1) treatment with an agent that is a) DNA, b) RNA or c) protein;

2) treating a population of cells which are a) cancerous cells, b) infected autoreactive antibody-producing cells, or c) hair follicle cells;

3) treating a patient for a) myocardial infarction, b) stroke, c) degenerative disease, d) brain injury, e) hypoxia, f) pathogenic infection, g) aging or h) hair loss.

DNA, RNA and protein are used for different purposes, and one is not required to use the other. The different cells are used for different purposes, grow differently and can be used for different purposes. The different diseases have different modes of operation, different therapeutic protocols and reagents and are material distinct and separate. Should applicants elect Group XV, applicants should elect a, b or c from species listed in 1), elect a, b or c from species listed in 2), and elect a, b, c, d, e, f, g or h from species listed in 3).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of

claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120.

mcw
February 11, 1999

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630